DEC - 4 2009

K091352
pg. 1 of 3

11 510(k) Summary

11.1 Sponsor's Name & Address

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

11.2 Official Correspondent

Balaka Das
Senior Specialist, Regulatory Affairs
Phone: 909-839-8599
Fax: 909-839-8804
Email: bdas2@its.jnj.com

11.3 Submission Date

May 6, 2009

11.4 Trade Name

SOUNDSTAR™ 3D Ultrasound Catheter

11.5 Common Name

Electrophysiology Mapping/Ultrasound Catheter

11.6 Classification Name/Product Code

Intravascular Ultrasound Catheter/OBJ

11.7 Classification

Class II

11.8 Predicate Device

SOUNDSTAR™ 3D Ultrasound Catheter (K070242) cleared on May 15, 2007.

K091352
pg 2 of 3

11.9 DESCRIPTION OF DEVICE

The Biosense Webster SOUNDSTAR™ 3D Ultrasound Catheter is a 90 cm 10F IntraCardiac Echo (ICE) Catheter with an acoustic array identical to the ACUSON AcuNav™ 10F Diagnostic Ultrasound Catheter. The catheter has a location sensor (providing location information to CARTO® EP Navigation Systems with ultrasound capability) and an ultrasound transducer (acquiring real time ultrasound images) embedded in the tip.

The SOUNDSTAR™ 3D Ultrasound Catheter has a bifurcated 'tail' originating from its handle. One leg terminates in the SOUNDSTAR tab connector, which connects via a Swiftlink™ cable to an ultrasound system. The other leg terminates in the CARTO® Hypertronic connector, which connects via a Patient Interface Unit (PIU) extension cable to the CARTO® Navigation System.

The SOUNDSTAR™ 3D Ultrasound Catheter, when connected to a CARTO® EP Navigation System with ultrasound capability, and the Sequoia or the Cypress Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO® electromagnetic acquired maps.

11.10 INDICATIONS FOR USE

The Biosense Webster SOUNDSTAR™ 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® EP Navigation Systems, the SOUNDSTAR™ 3D Catheter provides location information.

11.11 DESCRIPTION OF MODIFICATION

The modified SOUNDSTAR™ 3D Ultrasound Catheter is physically ***identical*** to the predicate device in terms of design, manufacturing methods, materials and performance. There are absolutely no changes to the device whatsoever. The only modification is to the labeling for the device to allow compatibility with multiple CARTO® EP Navigation Systems with ultrasound capability.

11.12 SUMMARY OF NONCLINICAL TESTS

All testing previously submitted for the SOUNDSTAR™ 3D Ultrasound Catheter still applies to the modified device as there were no changes to the design, materials, manufacturing methods or performance of the

device. Testing for compatibility with the CARTO® 3 EP Navigation Systems was submitted in the CARTO® 3 System 510(k). Therefore, no additional testing is submitted in this Premarket Notification.

11.13 SUBSTANTIAL EQUIVALENCE

The modified SOUNDSTAR™ 3D Ultrasound Catheter is identical to the previously cleared SOUNDSTAR™ 3D Ultrasound Catheter in that the devices:

- have the same intended use,
- use the same operating principle,
- use the same fundamental scientific technology,
- incorporate the same design,
- incorporate the same materials and construction,
- have the same shelf life, and
- are packaged using the same materials and processes.

In summary, the SOUNDSTAR™ 3D Ultrasound Catheter described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 0 4 2009

Biosense Webster, Inc.
Balaka Das, Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K091352
Trade/Device Name: SoundStar 3D Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: November 3, 2009
Received: November 5, 2009

Dear Ms. Das:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091352

Device Name: Soundstar 3D Ultrasound Catheter

Indications For Use:

The Biosense Webster SOUNDSTAR™ 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® EP Navigation Systems, the SOUNDSTAR™ 3D Catheter provides location information.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091352